FEB 01 2002 K014056

10. Salter Labs Modified Nebutech Nebulizer 510(k) Summary:

In accordance with 21 CFR section 807.92 Salter Labs is submitting the following safety and effectiveness summary.

1) Submitter Information

Duane Kazal
Director Operations
Salter Labs
100 W. Sycamore Road
Arvin, CA 93203
(661) 854-6818

2) Name of Device

Proprietary Name: Modified Nebutech Nebulizer (trade name to be determined)
Common Name is Nebulizer
Classification Name: Nebulizer

3) Substantially equivalent to: Modification to the Ultramist Nebulizer, K961476.

4) Device Description and System Overview:

The Salter Labs Modified Nebutech Nebulizer is a modification to the existing Salter Labs Nebutech Nebulizer (K961476). The Cone assembly has been changed to incorporate the lens deflector that was originally contained in the Lid assembly of the Nebutech Nebulizer and a horizontal baffle has been added. All materials used in the Modified Nebutech are identical to the original Nebutech product. The cone assembly fits against a molded stop so that it sits firmly on the base of the jar. There are no other modifications to this product.

This product is designed to be a single patient use device.

Table 1: Comparison of Modified Nebutech Materials to predicate Ultramist (Nebutech) Nebulizer:

Nebulizer Component:	Salter Labs Ultramist (Nebutech: K961476)	Salter Labs Modified Nebutech
Cup: material and Salter Labs component material specification number:	Polystyrene, FDA Compliance Compound	Polystyrene, FDA Compliance Compound Same as Nebutech
Top: material and Salter Labs component material specification number:	Polypropylene	Polypropylene, Same as Nebutech
Insert: material and Salter Labs component material specification number:	Polystyrene, FDA Compliance Compound, Transparent Green FDA Compliance Colorant	Polypropylene, Same as Nebutech Transparent Green FDA Compliance Colorant, Same as Nebutech

5) Principles of operation:

The modified Nebutech Nebulizer is a hand-held pneumatically powered nebulizer that consists of a Nebulizer Top that is screwed onto a Nebulizer Cup. The bottom of the cup has a fitting to accept a source of nebulizing gas. A third component, the cone assembly, fits over a mating conical surface within the Nebulizer Cup. The device consists of two basic operational units: the nebulizer portion (which forms and conveys an aerosol) and a reservoir portion (which contain non-aerosolized drug).

Cup: Nebulizer Portion:

The Nebulizer portion of the device consists of the following elements:

- the inlet port for the nebulizing gas;
- a liquid medication cup with a conical seat;
- a cone assembly, which rests on the seat and meters the liquid to the jet; and a jet which directs a high velocity stream of nebulizing gas and entrained liquid to an impact target which is integral to the cone assembly. A horizontal baffle is located directly above the impact target and helps transmit a consistent sized aerosol to the upper part of the nebulizer. This component is the primary modification to the existing Nebutech Nebulizer product, in that the target is now located on the cone assembly rather than on the aerosol reservoir section of the device.

The materials used in the Modified Nebutech Nebulizer are identical to the materials qualified for use in the original predicate Ultramist device, K961476.

Top: Aerosol Reservoir Section:

This portion of the Modified Nebutech Nebulizer contains an internal reservoir for the aerosol. The reservoir is equipped with an inhalation valve that opens to admit ambient air when the patient inhales and which closes when the patient exhales. Exhaled breath is thereby routed to an expiratory port, such as an exhalation valve in a mouthpiece or an expiratory port of a mask that is attached to the nebulizer. NOTE: The inhalation valve uses the identical valve assembly defined in the original Ultramist Nebulizer, K962476, in terms of design, specifications and materials used.

The Modified Nebutech Nebulizer contains a port for the fitting of an external mouthpiece that is identical to and serves the same purpose as the predicate Ultramist nebulizer. The mouthpiece, when attached, contains a breath-actuated exhalation valve which works in conjunction with the inhalation valve in the top of the nebulizer top to minimize re-breathing of expired gas. This allows the patient to utilize more of the aerosol that might otherwise be wasted if the nebulizer were connected to a conventional patient circuit.

6) Operation:

The nebulizer is disassembled and assembled according to product labeling. Medication is placed in the nebulizer cup when the unit is disassembled. The Nebulizer Housing is screwed onto the Cup and seated snugly and the supply line from the nebulizing gas source is then connected to the bottom of the nebulizer cup.

When pressurized nebulizing gas is applied to the nebulizer, the solution in the cup is sucked up between the mating surfaces of the cup and overlaying cone assembly and ejected at great velocity against the target. The liquid is broken into extremely small particles, forming an aerosol. A horizontal circular baffle integral to the cone adapter prevents large aerosol particles from passing into the upper portion of the nebulizer. These larger droplets form on the walls and internal baffles within the nebulizer and fall back into the cup for subsequent nebulization. Smaller particles occupy the space in the upper portion of the nebulizer and are inhaled by the patient. The aerosol particles that are inhaled are consistently sized and meet the requirements for respirable aerosol.

7) In-Vitro Performance Testing:

   Product performance testing was performed according to the "Reviewer Guidance for Nebulizers Metered Dose Inhalers, Spacers and Actuators (10-01-93)" and Salter Labs testing requirements. Product testing demonstrates that the Modified Nebutech Nebulizer is comparable and equivalent to the predicate device tested.

   All testing was performed in the Salter Labs R&D test laboratory according to documented test protocols. Comparative product testing was performed on the Pari LC Plus Nebulizer.

   Test results demonstrated that the Modified Nebutech Nebulizer was equivalent to the Pari LC Plus Nebulizer.

8) Clinical Testing: No clinical testing was performed on this product.

9) Software Validation: Not applicable: there is no software in this product.

10) Sterilization Validation: Not applicable: this product is sold and used as a non-sterile product.

11) Biocompatibility: All materials used in this device are identical to the Salter Labs Nebutech Nebulizers and are therefore appropriate for the intended use as described.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

FEB 01 2002

Mr. Duane Kazal
Salter Labs
100 W. Sycamore Road
Arvin, CA 93203

Re: K014056
Salter Labs Modified Nebutech Nebulizer
Regulation Number: 868.5630
Regulation Name: Nebulizer
Regulatory Class: II (two)
Product Code: CAF
Dated: January 17, 2002
Received: January 22, 2002

Dear Mr. Kazal:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

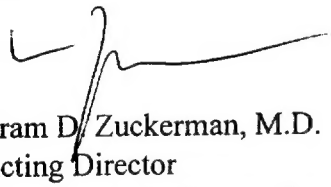
If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801 and additionally 21 CFR Part 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4646. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address http://www.fda.gov/cdrh/dsma/dsmamain.html

Sincerely yours,



Bram D. Zuckerman, M.D.
Acting Director
Division of Cardiovascular
and Respiratory Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

4. Indications for Use

Salter Labs Modified Nebutech Nebulizer

This product is a nebulizer used to generate aerosols that are delivered directly to the patient for breathing. Its use is indicated whenever a physician or healthcare professional administers or prescribes medical aerosol products to a patient using a Small Volume Nebulizer. This product is a single patient use, non-sterile prescription device and is designed to be used in either a hospital or homecare environment.

Division of Cardiovascular & Respiratory Devices
510(k) Number K016056